REMARKS

This Amendment is in response to the Office Action mailed September 1, 2004, having a three (3) month shortened statutory period for reply. A Petition for a One Month Extension of Time in accordance with 37 C.F.R.§§ 1.136(a) and 1.17(a) is submitted herewith.

Claims 1-11 and 13 are pending in this application. Claims 1-7, 10, 11 and 13 have been rejected and claims 8 and 12 are cancelled in the above-identified application.

Claims 1 and 2 have been amended for the sake of clarification and to correct for inadvertent typographical errors. No new matter has been added to the claims or specification of the above-identified application.

Attached herewith is a Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(b).

Applicant requests consideration and entry into the record of the following amendments and remarks.

Claim Rejections – 35 USC §112

Claims 1-8, 10, 11 and 13 are rejected under 35 U.S.C. §112, first paragraph, as the specification contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention.

In particular, the Examiner states that the specification, while enabling for compounds having a quinoline core (i.e., one of Z^1-Z^5 being other than CH or one of Z^1-Z^5 being CR^{1a} when R^{1a} is hydrogen), R^1 as methoxy and R^5 being alkyl, does not reasonably provide enablement for R^1 being alkoxy sybstituted by piperidyl, guanidine or other substituents other than methoxy; R^5 being hydroxylcycloalkyl, cyano, substituted phenyl alkyl or substituted benzoyl among others. The Examiner also states that the specification and claims have many substituents listed including natural amino acid side chains or their enantiomers, but only makes and enables the substituents, wherein R^1 is methoxy, Z^1-Z^5 is CH or CR^{1a}, wherein R^{1a} is hydrogen and R^5 being other than alkyl.

Applicants respectfully traverse this rejection.

However, in the interest of advancing prosecution and for the sake of clarification, applicants have amended claim 1 to delete the following specific functional group definitions associated with the term Z^5 as shown below:

> "additionally when Z^5 is CR^{1a}, R^{1a} may be (C_{1-4})alkyl-CO_2H or (C_{1-4})alkyl-$CONH_2$ in which the C_{1-4} alkyl is substituted by R^{12}; (C_{1-4})alkyl substituted by amino, cyano or guanidino; aminocarbonyl optionally substituted by hydroxy, (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl, (C_{2-6})alkenyl, (C_{1-6})alkylsulphonyl, trifluoromethylsulphonyl, (C_{2-6})alkenylsulphonyl, (C_{1-6})alkoxycarbonyl, (C_{1-6})alkylcarbonyl, (C_{2-6})alkenyloxycarbonyl, (C_{2-6})alkenylcarbonyl, or $CH(R^{13})CO_2H$ or $CH(R^{13})CONH_2$ optionally further substituted by (C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, aminocarbonyl(C_{1-6})alkyl or (C_{2-6})alkenyl; hydroxy(C_{1-6})alkyl; carboxy; cyano or (C_{1-6})alkoxycarbonyl; wherein R^{13} is a natural □-amino acid side chain, or its enantiomer".

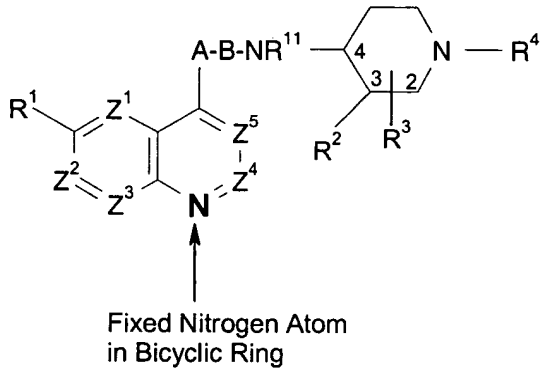
Amended claim 1 now also incorporates the definition of R^4 (i.e., where R^4 is defined in the specification as a group $-CH_2-R^5$), as defined in now cancelled claim 8, and deletes the following definitions associated with the functional group variable R^4:

> "R^4 is a group $-CH_2-R^5$ in which R^5 is selected from:
> (C_{1-12})alkyl; hydroxy(C_{1-12})alkyl; (C_{1-12})alkoxy(C_{1-12})alkyl; (C_{1-12})alkanoyloxy(C_{1-12})alkyl; (C_{3-6})cycloalkyl; hydroxy(C_{3-6})cycloalkyl; (C_{1-12})alkoxy(C_{3-6})cycloalkyl; (C_{1-12})alkanoyloxy(C_{3-6})cycloalkyl; (C_{3-6})cycloalkyl(C_{1-12})alkyl; hydroxy-, (C_{1-12})alkoxy- or (C_{1-12})alkanoyloxy-(C_{3-6})cycloalkyl(C_{1-12})alkyl; cyano; cyano(C_{1-12})alkyl; (C_{2-12})alkenyl; (C_{2-12})alkynyl; tetrahydrofuryl; mono- or di-(C_{1-12})alkylamino(C_{1-12})alkyl; acylamino(C_{1-12})alkyl; (C_{1-12})alkyl- or acyl-aminocarbonyl(C_{1-12})alkyl; mono- or di- (C_{1-12})alkylamino(hydroxy) (C_{1-12})alkyl; optionally substituted phenyl(C_{1-12})alkyl, phenoxy(C_{1-12})alkyl or phenyl(hydroxy)(C_{1-12})alkyl; optionally substituted diphenyl(C_{1-12})alkyl; optionally substituted phenyl(C_{2-12})alkenyl; optionally substituted benzoyl or benzoyl(C_{1-12})alkyl; optionally substituted heteroaryl or heteroaryl(C_{1-12})alkyl; and optionally substituted heteroaroyl or heteroaroyl(C_{1-12})alkyl;".

The Examiner states that the nature of the invention in the instant application has claims that embrace a diversity of chemically and physically distinct compounds and while some compounds are disclosed, there is insufficient guidance for preparing additional

compounds other than those defined as having a quinoline core (i.e., one of Z^1-Z^5 being other than CH or one of Z^1-Z^5 being CR^{1a} when R^{1a} is hydrogen), R^1 as methoxy and R^5 being alkyl.

For the record, applicants respectfully note that the Examiner's statement with regard to the fact that the present specification, "while enabling for compounds having a quinoline core (i.e., one of Z^1-Z^5 being other than CH or one being CR^{1a} when R1a is hydrogen)" is not a correct statement, because a quinoline core is represented or defined when all Z1 to Z5 = CH or CR1a, because the generic structure formula (I) of the present invention already includes a fixed nitrogen group at one of the bicyclic functional group positions:



(I)

However, with regard to the scope of the remaining functional group terms associated with formula (I) of the present invention (i.e., not discussed above and which are outside of the scope of definitions related to the terms R1 is methoxy, Z1-Z5 being CH or CR1a wherein R1a is hydrogen and R5 being alkyl), it is well known that the first paragraph of 35 U.S.C. §112 does not require specific exemplification of all subject matter within the scope of the broad claims. *In re Robins*,166 U.S.P.Q. 552, 555 (CCPA 1970).

The inclusion of a number of representative examples in the specification is just one way of teaching how to make and/or use the invention. *Id.* Thus, the claims should not be limited to the compounds specifically exemplified in the specification when there is a clear disclosure of a broad genus.

Examples from the chemical literature show support for not limiting the claims to specifically exemplified specification. For example, structurally non-identical chemical compounds with attached chemical substituent groups of similar scope to those of the present invention are exemplified in International Appln. WO 99/37635 or corresponding U.S. Pat. Appln. Serial No. 09/600,984 which discloses a quinoline compound of formula (I), which is further substituted with a variety or broad scope of substituent groups at the same substituent position corresponding to the variable R1 substituent of Formula (I) the present invention. International Appln. WO 00/21948 or U.S. Pat. Appln. Serial No. 10/032,403 (i.e., which is a continuation of U.S. Pat. Appln. Serial No. 09/802,275), also discloses compounds corresponding to those of WO9937635, but where the quinoline core is replaced by a bicyclic ring where one of Z1-Z5 is N. Moreover, it also worth noting that each of the aforementioned International Patent Applications discussed supra relate to compounds that exhibit antibacterial biological activity.

Moreover, in the instant application, applicants have provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed compounds for treating a bacterial infection using a compound of formula (1) of the claimed invention. In addition to the working examples 1 to 7 disclosed in the specification (see, page 20, lines 1-32 to page 24, lines 1-28), applicants describe a general process for preparing compounds of formula (I) compounds and pharmaceutically acceptable derivatives thereof (see, page 9, lines 21-31 to page 10, lines 1-16 of the specification). The specification also discusses variations on the aforementioned process for derivative syntheses via use of different functional groups or different synthetic routes (see, as described from pages 10, lines 17-33 to page 17, lines 1-29 of the specification). Moreover, some starting materials for the various aromatic and heterocyclic groups can be purchased commercially or prepared by routine methods well known to those of ordinary skill in the art (i.e., e.g., method examples can be found in standard reference books, such as the COMPENDIUM OF ORGANIC SYNTHETIC METHODS, Vol. I-VI (published by Wiley-Interscience).

In light of the foregoing, applicants have set forth detailed syntheses for preparation of compounds of the present invention and given the detailed disclosure of

the genus, synthetic methods provided in the specification, and commercial availability of starting materials, one of ordinary skill in the art would have ample guidance for the synthesis of compounds falling within the genus of the present invention, which may be synthesized from starting materials which are commercially available or prepared by routine methods.

The Examiner also states that little testing data is provided for any of the compounds listed in the specification and that the generic claims are much broader in scope than is represented by the testing.

Applicants submit that generic representations of utility have a preferred status in patent law. Applicants' assertions of utility and operativeness are to be accepted as accurate absent evidence to the contrary. *Wettstein v. Campbell*, 139 U.S.P.Q. 341 (BOPI 1962). Applicants have given, on page 24, lines 21-29 that the biological activity of test compounds against various organisms was determined. Given the disclosure of appropriate test systems, Applicants have fulfilled the "how to use" requirement under 35 U.S.C. §112.

Applicants maintain that they have fully provided direction and guidance in teaching one of ordinary skill how to make and use all the claimed compounds of formula (I) of the present invention for use as antibacterial agents in the treatment of bacterial infections via the originally filed disclosure.

In light of the foregoing, applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

Claim 2 is rejected under 35 U.S.C. § 112, 2nd para., for insufficient antecedent basis being indefinite and for failing to particularly point out and distinctly claim the invention.

For the record, applicants note that the identical claim 2 was amended in a previous April 28, 2003 Amendment made during the prosecution of the parent application, U.S. Appln. Serial No. 10/031,768, from which the present application derives priority. The April 28, 2003 amendment to claim 2 was made in response to an Examiner's rejection under 35 U.S.C. § 112, 2nd para., that claim 2 was ambiguous (see April; 28, 2003 Amendment and pages 2, lines 2-7, page 4, lines 5-8 and page 5, lines 9-13). The Examiner removed the rejection after that amendment to claim 2.

In the November 24, 2003 Preliminary Amendment filed in the present application, applicants inadvertently omitted keeping the changes made to claim 2 in the previous April 28, 2003 Amendment.

In the present response to overcome the identical rejection, applicants have amended claim 2 to reflect the identical amendments made in the April 28, 2003 Amendment.further note that when the Preliminary Amendment. Amended claim 2 now recites

"A compound according to claim 1 wherein:

(a) Z^1 is N, Z^3 is CH or CF, and Z^2, Z^4, and Z^5 are CH,

(b) Z^3 is CH or CF and Z^1, Z^2, Z^4, and Z^5 are CH, or

(c) Z^5 is N, Z^3 is CH or CF, and Z^1, Z^2, and Z^4 are CH."

Support for this amendment is found at page 5, lines 9-13 and 26 of the specification.

In light of the above, applicant requests that the above rejection under 35 U.S.C. § 112, 1st and 2nd paragraphs, be withdrawn.

Allowable Subject Matter

Claim 9 is indicated to be allowable over the prior art of record.

Applicants thank the Examiner for noting on the record that the closet prior Myers reference only teaches similar quinoline compounds, but neither anticipates nor renders obvious compounds taught in claim 9 of the present invention.

CONCLUSION

In view of the above amendments and remarks, applicants believe that the claims of the present application are in condition for allowance and is earnestly solicited.

If any additional fees or charges are required authorization is hereby granted to charge any necessary fees to Deposit Account No. 19-2570 accordingly.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,

Grace C. Hsu
Attorney for Applicants
Registration No. 51,336

GLAXOSMITHKLINE
Corporate Intellectual Property-UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone: (610) 270-4650
Fax: (610) 270-5090